REMARKS

Claims 69-75, 77-95 and 97-104 are pending in the instant application. Claims 69, 70 and 85 have been amended to place the application in condition for allowance and/or in better form for appeal. The amendments are fully supported by the specification as filed. No new matter has been introduced.

The amendment filed July 25, 2005 has been objected to under 35 U.S.C. §132(a) as allegedly introducing new matter into the disclosure. While not acquiescing to the Examiner's objection, the Applicants have amended the claims to recite, in part, as follows "a dosage of the substance for achieving a systemic bioavailability of the substance is reduced". The amended claims are fully supported by the specification as filed, as detailed in the discussion below. In view of the claim amendments, the Examiner's objection should be withdrawn.

Rejection of Claims 75, 77-95 and 97-104 Under 35 U.S.C. 112, First Paragraph, Should be Withdrawn

Claims 69-75, 77-95 and 97-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the specification provides no link between systemic distribution of a substance and percent reduction of dosage of that substance. The claims as amended are fully supported by the specification and the rejection should be withdrawn.

The test for sufficiency of written description is whether the disclosure of the application 'reasonably conveys to the artisan that the inventor had possession' of the claimed subject matter. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. (BNA) 1089, 1096 (Fed. Cir. 1983); accord *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563; *see also*, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985). The Court of Appeals for the Federal Circuit has repeatedly considered the written description requirement and consistently found that exacting detail is not necessary to meet the requirement: If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, the adequate

written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

The currently pending claims are directed to a method of delivering a substance into an intradermal compartment of a subject's skin, wherein a dosage for achieving systemic bioavailability of the substance is reduced by at least 10% compared to when the substance is delivered to a subcutaneous compartment of the human subject's skin. Applicants assert that the specification provides full support for the currently pending claims. In particular, there is support for a link between higher bioavailability of substances delivered via intradermal administration and percent reduction of dosage.

The specification defines intradermal delivery to mean administration of a substance to the dermis in such a manner that it becomes systemically bioavailable (see, *e.g.*, ¶ [0016] of the instant specification). Systemic bioavailability of a substance is defined as the total amount of a given dosage that reaches the blood compartment and can be measured by determining the blood or plasma levels of the substance (see, *e.g.*, ¶ [0013] of the instant specification). The instant specification further describes that delivery of a substance at greater depths -- the subcutaneous region -- would result in reduced absorption and thus reduced systemic bioavailability (see, *e.g.*, ¶ [0016] of the instant specification). The direct benefit of the invention is that ID administration with enhanced bioavailability allows equivalent biological effects while using less active agent (see, *e.g.*, ¶ [0018] of the instant specification). Furthermore, higher bioavailability may allow reduced overall dosing (see, *e.g.*, ¶ [0018] of the instant specification). The effective amount of a substance necessary to treat a symptom may be reduced 10%, 20% or 30% compared to subcutaneous delivery (see, *e.g.*, ¶ [0018] of the instant specification). Furthermore, Example VII of the instant specification shows that to achieve systemic bioavailability of Humalog insulin, only 77.5% of the subcutaneous dose needs to be administered intradermally and to achieve systemic bioavailability of Neupogen, only 70.1% of the subcutaneous dose needs to be delivered intradermally. Thus, the specification establishes that a dose of a substance for achieving systemic bioavailability of that substance via intradermal delivery is reduced by at least 10, 20 or 30 percent as compared to subcutaneous delivery.

In view of the arguments above, the claims do contain subject matter which is described in the specification is such a way as to reasonably convey to one skilled in the artisan that the inventors, at the time the application was filed, had possession of the claimed

invention and the rejection of claims 69-75, 77-95 and 97-104 under 35 U.S.C. 112, first paragraph, should be withdrawn.

CONCLUSION

In light of the above amendments and remarks, the Applicants respectfully request that the Examiner enter the amendments and consider the remarks made herein. Withdrawal of all rejections, and an early allowance is earnestly sought. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted,

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